DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 30, 2014

Ecolab, Inc.
Ms. Jennifer Willner
Senior Director, Regulatory Affairs
370 Wabasha Street North
St. Paul, MN 55102

Re: K142173
Trade/Device Name: ORS Scope Pillow Warmer Drape
Regulation Number: Unclassified
Regulation Name: Equipment Cover
Regulatory Class: Unclassified
Product Code: LHC
Dated: December 3, 2014
Received: December 4, 2014

Dear Ms. Willner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142173

Device Name

ORS Scope Pillow Warmer Drape

Indications for Use *(Describe)*

The ORS pillow drape is a single-use disposable device intended for use as an accessory for ORS Solution Warmers which is designed to hold the optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.

The following model(s) are included: ORS-400 and ORS-400N

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary – K142173

ORS Scope Pillow Warmer Drape

As required by 21 CFR 807.92.

Date: August 6, 2014

Administrative Information

Submitter: Ecolab, Inc.

Establishment Registration Number: 1043582

Contact Person: Jennifer Willner, RAC
370 Wabasha Street North
St. Paul, MN 55102-1390
Sr. Director, Regulatory Affairs - Healthcare
651.250.4348

Device Identification

Device Name:	ORS Scope Pillow Warmer Drape
Common Name:	Equipment Cover
Device Classification Name:	Warmer, Irrigation Solution
Device Classification:	Unclassified
Classification Product Code:	LHC
Panel:	General and Plastic Surgery
Classification Regulation:	Pre-Amendment
Performance Standards:	No Recognized Consensus Standards
Predicate Device:	ORS Warming Drape cleared on 06/27/2002 via K021288 and ORS Endoscope Holder cleared on 08/30/2005 via K051979

Device Description

The ORS-400N Scope Pillow™ Warmer Drape is a single-use disposable device provided non-sterile to secondary processors, who then package, label and sterilize the device. The Scope Pillow Warmer Drape is an accessory/equipment drape for use with the ORS-2057 Irrigation Solution Warming System which is designed to both protect ORS surgical fluid warmers from contamination during various procedures as well as hold the optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.

The drape material is the identical polyurethane film that is used on all standard ORS Warmer Drapes (K021288). A soft polyurethane foam pillow is integrated within the polyurethane drape and has no direct or indirect patient contact. The pillow (endoscope holder) is designed to provide stable positioning of scope(s) during warming and prevents one or more scopes from rolling or tipping while the scope rests in the fluid warmer during the procedure (***Figure 5-1***).

Figure 5-1 Scope Pillow Warmer Drape

The ORS-400 and ORS-400N model drapes are identical with the exception of how they are packaged and labeled. The ORS-400 model consists of drapes individually packaged in labeled peel pouches or header bags which are stacked inside a double poly-lined corrugate case with Instructions for Use (IFU) insert and sterilized by an Ecolab subcontractor before it is released for sale. The ORS-400N model consists of the identical drapes which are individually wrapped in a poly tie secured by a product ID label and stacked inside a double poly-lined corrugate case with IFU insert that does not get sterilized before it is released for sale to kit packer customers. The IFU insert differs between the two models in that the ORS-400N contains sterilization instructions for kit packer customers to evaluate their sterilization process as it applies to placing the product in their commercial procedure kits.
NOTE: Both device models are designed and intended to be used by clinical staff in sterile condition.

510(k) Discussion

This 510(k) submission requests clearance for the manufacture and distribution of Non-Sterile ORS-400N Scope Pillow Warmer Drape (equipment cover with integrated pillow/endoscope holder). The non-sterile drape will be sold in bulk packaging to

secondary processors who will then package, label and sterilize the drapes as required under the regulation prior to distribution to end users. The non-sterile drape has the identical polyurethane drape material, and identical drape function as the predicate drape (K021288). The pillow (endoscope holder) provides the same holding function as the predicate Endoscope Holder (K051979). Therefore, the fundamental scientific technology of this equipment drape remains unchanged. The Substantial Equivalence Table (***Table 5-1***) is provided below.

Table 5-1: Substantial Equivalence

Property or Characteristic	**Proposed Device – Non-Sterile ORS-400N Scope Pillow™ Warmer Drape**	**Predicate Device – ORS-1000LD Equipment Cover**	**Predicate Device – ORS Endoscope Holder**
510(k) No.	**This 510(k) Submission**	**K021288**	**K051979**
Device Name	**ORS-400N Scope Pillow Warmer Drape**	ORS-1000LD Warming Drape	ORS Model 6000 Endoscope Holder
Indications for Use	The ORS pillow drape is a single-use disposable device intended for use as an accessory for ORS Solution Warmers which is designed to hold the optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.	The ORS-1000LD Leak Detection Drape is an equipment cover for the ORS-2000LD Solution Warmer. This is a single use product supplied sterile. This device is intended for use during various surgeries where warm irrigation solution is required.	The ORS 6000 Endoscope Holder is a single use disposable device used as an accessory for ORS Solution Warmers. The ORS 6000 Endoscope Holder is designed to hold the optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.
Conditions of Use	Rx Only, Single Use, Disposable	Identical	Identical
Materials	Polyurethane Film Polyurethane Foam	Identical Film	Thermoplastic polyester resins
Principle of Operation	Covers surgical solution warmers and endoscope holder	Covers surgical solution warmers	Endoscope Holder

Property or Characteristic	Proposed Device – Non-Sterile ORS-400N Scope Pillow™ Warmer Drape	Predicate Device – ORS-1000LD Equipment Cover	Predicate Device – ORS Endoscope Holder
Packaging	Bulk packaged in poly bag in quantities up to 10	Individually packaged in poly/Tyvek peel pouches	Individually packaged in poly/Tyvek peel pouches
Sterilized	No; intended to be sterilized before distribution to end user	Yes; provided in sterile condition via EO at SAL 10^{-6}	Yes; provided in sterile condition via EO at SAL 10^{-6}

Performance Data Summary

Table 5-2: Performance Data Summary of the Non-Sterile ORS-400N Scope Pillow Warmer Drape

Requirement	Specification	Method	Result
Functional Performance Requirements	Dimensional Requirements: ORS-400N (44 in. x 66 in.)	Acceptable results following visual inspection during V&V testing; VVR-14-0002 V&V Summary Report, Project 8 Track	Pass
	Drape remains intact (free from holes or other defects that would compromise the sterile barrier)	Acceptable results following visual inspection during V&V testing; VVR-14-0002 V&V Summary Report, Project 8 Track	Pass
Packaging	Packaging Configuration: 10 per case, double poly bagged	Packaging Configuration per: ORS-400N_DWG; Acceptable results following visual inspection during V&V testing; VVR-14-0002 V&V Summary Report, Project 8 Track	Pass
	Product must be received by customer with folds intact	Acceptable results following visual inspection during V&V testing; documented in V&V summary report VVR-14-0002	Pass
	Simulated Distribution Test	ASTM D4169-09 (Distribution Cycle 2, Assurance Level 1) Simulated Distribution Test	Pass

Requirement	Specification	Method	Result
		(PKG 001F) documented in Packaging Engineering Report # REPT-18430	
	Inspection for Drape Damage	Acceptable results following visual inspection during V&V testing; documented in the V&V summary report VVR-14-0002	Pass
Labeling	Master carton label is present and per specification	Master label specifications: ORS-400NMASTER Acceptable results following visual inspection during V&V testing; documented in the V&V summary report VVR-14-0002.	Pass
	Ink (non-smudge/smear)	Acceptable results following visual inspection during V&V testing; documented in V&V summary report VVR-14-0002	Pass
	Insert Sheet/IFU is present and per specification	Insert Sheet/IFU specifications: ORS-400N-INSERT SHEET	Pass
	Product Identification label includes product code and Ecolab Logo	Product Identification label specification: ORS-400NMISC	Pass

Statement of Equivalence

The Non-Sterile ORS Scope Pillow Warmer Drape performs as intended using the identical principles of operation as the predicate devices. Specifically, it is designed to protect ORS surgical solution warmers from contamination during various procedures as well as hold the optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece. Differences between the Non-Sterile ORS Scope Pillow Warmer Drape and the sterile version (packaging and labeling), as well as the predicate devices (two separate components used together), do not raise any new questions of safety or efficacy when secondary processors sterilize the product as instructed. Based on the risk analysis, review of the product labeling, and successful performance testing (*Table 5-2*), the ORS Scope Pillow Warmer Drape is substantially equivalent to the legally marketed ORS Warming Drape (K021288) and ORS Endoscope Holder (K051979). The fundamental scientific technology of the device remains unchanged.